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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/668,749	09/23/2003	Hui Wang	10030304-1	2131

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EXAMINER

CLOW, LORI A

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 04/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	10/668,749		WANG, HUI	
	Examiner		Art Unit	
	Lori A. Clow, Ph.D.		1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claim Status

Claims 1-21 are currently pending.

Priority

Priority to US Provisional Application 60/412,959, filed 23 September 2002, is acknowledged.

Drawings

The drawings submitted 23 September 2003 are hereby accepted.

Claim Objections

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claim 22 has been renumbered as claim 21.

Claim 18 is objected to because of the following informalities: Claim 18 reads “a data system is further operative to analyze...**comparing**...and determine”. This should read “ a system is further operative to “analyze...**compare**..and determine”. Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-21 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

In the instant case, the claims include nonfunctional descriptive material of which no requisite functionality is present to satisfy the practical application requirement of statutory subject matter. Merely claiming nonfunctional descriptive material, i.e., abstract ideas, stored in a computer-readable medium, in a computer, or on an electromagnetic carrier signal does not make it statutory. See *Diehr* (referenced below). In the instant case, the claims do not result in a physical transformation to a different state or thing. There is no stated outcome to the claimed method of performing a nanopore data analysis such that a concrete, tangible, and useful result is apparent. The system which is operative for data analysis does not generate an outcome which is concrete, tangible and useful, as well. The system is analyzing a distribution without any physical transformation of that data. The claims are, therefore, non-statutory

For claims including such excluded subject matter to be eligible, the claim must be for a practical application of the abstract idea, law of nature, or natural phenomenon. *Diehr*, 450 U.S. at 187, 209 USPQ at 8 (“application of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection.”); *Benson*, 409 U.S. at 71, 175 USPQ at 676 (rejecting formula claim because it “has no substantial practical application”).

To satisfy section 101 requirements, the claim must be for a practical application of the § 101 judicial exception, which can be identified in various ways:

1) The claimed invention “transforms” an article or physical object to a different state or thing.

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2) The claimed invention otherwise produces a useful, concrete and tangible result, based on the factors discussed below.

Practical Application That Produces a Useful, Concrete, and Tangible Result

For eligibility analysis, physical transformation “is not an invariable requirement, but merely one example of how a mathematical algorithm [or law of nature] may bring about a useful application.” AT&T, 172 F.3d at 1358-59, 50 USPQ2d at 1452... In determining whether the claim is for a “practical application,” the focus is not on whether the steps taken to achieve a particular result are useful, tangible and concrete, but rather that the final result achieved by the claimed invention is “useful, tangible and concrete.” (1) “USEFUL RESULT” For an invention to be “useful” it must satisfy the utility requirement of section 101. The USPTO’s official interpretation of the utility requirement provides that the utility of an invention has to be (i) specific, (ii) substantial and (iii) credible. MPEP § 2107 and Fisher, 421 F.3d at ___, 76 USPQ2d at 1230 (citing the Utility Guidelines with approval for interpretation of “specific” and “substantial”). (2) “TANGIBLE RESULT” The tangible requirement does not necessarily mean that a claim must either be tied to a particular machine or apparatus or must operate to change articles or materials to a different state or thing. However, the tangible requirement does require that the claim must recite more than a § 101 judicial exception, in that the process claim must set forth a practical application of that § 101 judicial exception to produce a real-world result. Benson, 409 U.S. at 71-72, 175 USPQ at 676-77 (invention ineligible because had “no substantial practical application.”). “[A]n application of a law of nature or mathematical formula to a ... process may well be deserving of patent protection.” Diehr, 450 U.S. at 187, 209 USPQ at 8 (emphasis added); see also Corning, 56 U.S. (15 How.) at 268, 14 L.Ed. 683 (“It is for the discovery or invention of some practical method or means of producing a beneficial result or effect, that a patent is granted . . .”). In other words, the opposite meaning of “tangible” is “abstract.” (3) “CONCRETE RESULT” Another consideration is whether the invention produces a “concrete” result. Usually, this question arises when a result cannot be assured. In other words, the process must have a result that can be substantially repeatable or the process must substantially produce the same result again. In re Swartz, 232 F.3d 862, 864, 56 USPQ2d 1703, 1704 (Fed. Cir. 2000) (where asserted result produced by the claimed invention is “irreproducible” claim should be rejected under section 101). The opposite of “concrete” is unrepeatable or unpredictable.

See also:

http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/guidelines101_20051026.pdf

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites “providing a sample including target polymers and non-target polymers and a nanopore device”. It is unclear as to how a nanopore device can be a sample, as is presently claimed. Clarification is requested.

Claim 5 recites “determining a ration of phosphorylated target polynucleotide”. There is insufficient antecedent basis in the claim for “phosphorylated target”. Clarification is requested.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for performing nanopore analysis on polynucleotide data, does not reasonably provide enablement for performing nanopore analysis on polypeptide data, as claimed in claim 1 and 15. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use or make the invention commensurate in scope with these claims.

In *In re Wands* (8 USPQ2d 1400 (CAFC 1988)) the CAFC considered the issue of enablement in molecular biology. The CAFC summarized eight factors to be considered in a determination of "undue experimentation". These factors include: (a) the quantity of

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experimentation necessary; (b) the amount of direction or guidance presented; (c) the presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the relative skill of those in the art; (g) the predictability of the art; and (h) the breadth of the claims.

In considering the factors for the instant claims:

a) In order to practice the claimed invention one of skill in the art must be able to perform nanopore data analysis by providing a sample that includes target polymers and non-target polymers which are selected from polynucleotides or from polypeptides. For the reasons discussed below, this constitutes undue experimentation.

b) and c) The specification provides examples for performing nanopore data analysis using polynucleotides. For example, at page 13, the data analysis method and system performs a distribution analysis on polynucleotide data such that phosphorylation states may be determined. The specification, however, does not teach that such a method or system can perform the analysis using polypeptides and polypeptide data.

d) The invention is drawn to a method and system to analyze polynucleotide or polypeptide data.

e) and g) It would have been well known in the art that nanopore data analysis has been used to discriminate between various types of polynucleotides. For instance, Meller et al. (PNAS (2000) Vol. 97, No. 3, pages 1079-1084) teach a method by which a variety of DNA polymers different types of polynucleotides in a sample can be determined by the translocation of the polynucleotides across a nanopore (page 1079, Abstract).

f) The skill of those in the art of molecular biology is high.

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h) The claims are drawn to nanopore analysis of polypeptides and polynucleotides.

However, the claims are not enabled for the analysis, using nanopore techniques, of polypeptides.

The skilled practitioner would first turn to the instant specification for guidance to practice methods. However, the instant specification does not provide specific guidance to practice the embodiments of polypeptide analysis using nanopores. As such, the skilled practitioner would turn to the prior art for such guidance, however, the prior art teaches only the analysis of polynucleotides using nanopore technology. Finally, said practitioner would turn to trial and error experimentation. Such represents undue experimentation

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 10, 12, 15, 16, 20 and 21 are rejected under 35 U.S.C. 102(a) as being anticipated by WO 02/42496 (Haussler et al.) (30 May 2002, International Publication Date).

In regard to claims 1, 2, 10, 15, 16, 20 and 21 Haussler teaches methods and devices for characterizing DNA molecules using a nanopore device. The characterization of nucleic acids through the nanopore device may include assigning a signature to the nucleic acid, wherein the

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signature may take various forms, including raw data values, manipulated sets of data values, and the like (page 8, lines 17-24). The signature may be screened against a reference signature to identify and observed signature (page 15, lines 13-18). The analysis includes distribution analysis (page 23-29 (Gaussian curve generation). The system may be automated and include computing means mad of hardware and software (page 18, lines 1-10).

Claims 1, 2, 10, 12, 15, 16, 20 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Meller et al. (PNAS (2000) Vol. 97, No. 3, pages 1079-1084).

In regard to claims 1 and 15, Meller teaches introducing DNA samples to a nanopore device whereby data are analyzed via software to yield a distribution pattern (page 1080, column 1; Figure 2; page 1082, column 1, 2nd paragraph).

In regard to claims 2 and 10, Meller teaches the analysis of data clusters within a distribution (page 1080, column 1, Results and Discussion (i) and (ii)).

In regard to claim 12, Meller teaches the distribution as indicative of polymers of the same length (page 1081, column 1, paragraph 2).

In regard to claim 20, Meller teaches the storage of nanopore data (page 1080, column 1, paragraph 1).

In regard to claim 21, Meller teaches a means for analyzing the distribution data (page 1080, column 1, paragraph 1).

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG

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30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571) 272-0718.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

March 18, 2006

Lori A. Clow, Ph.D.

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Lori A. Clow

Patent Examiner